510(k) Summary

K101429

SEP 15 2010

SUBMITTED ON BEHALF OF:

Company Name: **Ceracarta S.p.A.**
Address: **Via Secondo Casadei,14 47122 Forlì-ITALY**
Telephone: **+39- 0543- 780055**
Fax: **+39- 0543- 781404**

by: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: **715-549-6035**
Fax: **715-549-5380**

CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: **May 19, 2010**

TRADE NAME: **ECO SUPERGEL® (and various other proprietary trade names)**
COMMON NAME: ultrasound gel
CLASSIFICATION NAME: ultrasound gel
PRO CODE: IYO

SUBSTANTIALLY EQUIVALENT TO: **ECO SUPERGEL** water-soluble gel for ultrasound systems is substantially equivalent to the Parker Laboratories AQUASONIC 100 (K802146).

DESCRIPTION of the DEVICE: The **ECO SUPERGEL** is a water-soluble gel (transmission media) for diagnostic tests and therapies involving ultrasound systems.

INDICATIONS FOR USE:

ECO SUPERGEL® is a transmission gel media , used with ultrasonic pulsed echo imaging systems. The gel, when applied on the defined area of the body, facilitates the use of the system, which is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.

SUMMARY of TESTING:

- Bench Testing for comparative pH and viscosity.

-Stability tests to light, ambient temperature ,heating, cooling and thermal shocks.

-Challenge test-evaluation of the microbiological stability.

-TVC test ("Evaluation of total vital count,of yeast and moulds test").

-Biocompatibility test:

- Test on the standard ISO 10993 ;
- The Repeated Patch Test-Clinical evaluation of irritating potency of a product for the skin and of its sensitization potency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ceracarta SPA
% Ms. Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
STILLWATER MN 55082

SEP 15 2010

Re: K101429
Trade/Device Name: ECO Supergel
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: August 19, 2010
Received: August 23, 2010

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K101429

SEP 15 2010

510(k) Number (if known): 101429

Device Name: ECO Supergel

Indications for Use:

ECO SUPERGEL® is a transmission gel media used with ultrasonic pulsed echo imaging systems. The gel, when applied on the defined area of the body, facilitates the use of the system, which is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) ODUD

Division Sign-Off

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101429

Page 1 of 1